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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/010,246 | 12/06/2001 | Robert Sixto JR. | SYN-064C | 5866 |
| 24131 | 7590 | 01/05/2005 | EXAMINER | |
| LERNER AND GREENBERG, PA | | | PANTUCK, BRADFORD C | |
| P O BOX 2480 | | | ART UNIT | PAPER NUMBER |
| HOLLYWOOD, FL 33022-2480 | | | 3731 | |

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/010,246 | SIXTO ET AL. | |
| | Examiner | Art Unit | |
| | Bradford C Pantuck | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on November 12, 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10, 17, 18 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7, 17, 18, 21-26, and 28 is/are rejected.
- 7) Claim(s) 8-10, 27 and 29-31 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 4, 5, 7, and 21-26, are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,575,802 to McQuilkin et al. Regarding Claims 1, 21, 22, McQuilkin discloses a surgical clip with a first arm (12), a second arm (142), and a U-shaped bridge (16) connecting them [see Fig. 1; Column 1, lines 55-67]. McQuilkin discloses a deformable retainer (deformable particularly at hinge 144) extending from arm (142). The deformable retainer (140/144/126/128) has a length greater than π times the distance between the arms when the arms are substantially parallel [as shown in Fig. 2]. The distance between the arms is 2 mm [Column 3, line 11], and the length of the retainer portion (140), as measured from the hinge in an arcing trajectory to the edge (152) is significantly greater than 3 times the distance between the parallel arms. Examiner estimates that the length of the retainer portion (140) is 11 mm.
2. Regarding Claims 2 and 23, McQuilkin discloses a surgical clip with a retainer having a thickness smaller than the thickness of the first arm. The thickness of the retainer is measured at hinge (144). The first arm has a thickness of 3 mm and the

hinge portion of the retainer has a thickness of 1mm [Column 3, lines 10 and 13; Fig. 2].

3. Regarding Claim 4 and 25, McQuilkin discloses a retainer with a sharp tip. Retainer portion (140) has a sharp tip at tooth (150) and retainer portion (126/128) has a sharp tip at tooth (126).

4. Regarding Claims 5 and 26, McQuilkin discloses a retainer that is decouplable from one of the arms. If one were to disassemble hinge (16), then one would sever one arm from the other, decoupling the first arm (12) from the retainer (140).

5. Claims 17 and 18, are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,430,997 to DiGiovanni et al. DiGiovanni discloses a multiple clip applier for applying clips as disclosed by the applicant. DiGiovanni's clips (11) each have a first arm, a second arm, and a U-shaped bridge connecting them. Each clip has a deformable ("deflectable") retainer at its end [Column 4, lines 46-54]. Each retainer has a length of at least π times the distance between the arms when the arms are substantially parallel, as shown in Figure 5A. As is observable from Fig. 5A, the average distance between the two arms is much less than the length of the retainer, as measured perpendicular from the longitudinal axis of the clip [see Attachment #1].

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3-6, 21-25, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Publication No. US 2002/0104199 A1 to Chen. Chen discloses a first arm, a second arm, a U-shaped bridge connecting them, and deformable retainers extending from each arm, as labeled in Attachment #2. Since the clip is made out of "metal wire" the whole clip can be characterized as deformable. The clip is of a similar construction to the common paper clip, which is commonly known to be easily bendable. No structure is given to the word "retainer" in claim 1, and therefore anything that is capable of retaining something can be considered a retainer. Each retainer (labeled in Attachment #2) has a sharp tip. The deformable retainers each have a length more than 3.14 times the distance between the first arm and the second arm.
7. Regarding Claims 5 and 6, the retainer could be wrapped around either or both arms and be maintained by friction.

Allowable Subject Matter

8. Claims 8-10, 27, and 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

10. Applicant's arguments, see "Remarks", filed November 12, 2004, with respect to the rejections under Alessi and Wilson have been fully considered and are persuasive. The rejections of claims with these Patents have been withdrawn.

11. Applicant's arguments filed November 12, 2004 with respect to the rejection under U.S. Patent No. 5,575,802 to McQuilkin et al. have been fully considered but

they are not persuasive. Examiner maintains his position that, the deformable retainer (140/144/126/128) has a length greater than π times the distance between the arms when the arms are substantially parallel [as shown in Fig. 2]. Whether the distance between jaws 12 and 14 is zero (as Applicant claims) or the thickness of the resilient rubber lining (as Examiner claims) is irrelevant. The point remains that McQuilkin's retainer element extends *at least* (i.e., *more than*) π times the distance between the arms 12 and 14. The length the retainer extends past arm 14 (in the axial direction) is most clearly greater than zero ($\pi \times$ zero = zero), and the said length is also very clearly greater than π times the combined thickness of the two resilient rubber linings [see Fig. 2].

12. Similarly, Applicant's arguments filed November 12, 2004 with respect to the rejection under U.S. Patent No. 4,430,997 to DiGiovanni et al. have been fully considered but they are not persuasive. Examiner fails to see the significance of Applicant's arguments that the distance between the two clamping arms is zero. The proximal end of the clip [see Fig. 5A] clearly does form a U shape, whether the distance between the arms is zero or a number greater than zero.

13. Applicant's arguments filed November 12, 2004 with respect to the rejection under Publication No. US 2002/0104199 A1 to Chen have been fully considered but they are not persuasive. Chen discloses a deformable retainer that extends perpendicularly from the end of one of the arms. With reference to Fig. 4, if component (11) is the U-shaped bridge and component (10) is the first arm, component (12) is the deformable retainer. Component (12) forms an elbow with

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another long section and then forms another elbow, and so forth and so on, eventually forming 3 more complete loops. Because the clip is deformable, the user could straighten out members 12, 21, 31, 41, 20, 30, and 40, thus forming one long straight “retainer” capable of retaining tissue and extending from the end of “first arm” 10 in a *single direction*. Arguing that Chen’s clip is not deformable is akin to arguing that a common paper clip is not deformable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
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December 22, 2004

Z
ANHTUANT.NGUYEN
PRIMARY EXAMINER

12/23/04